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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,712	01/17/2002	John W. Shell	8350-0001	1400

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

RESTRICTION / ELECTION **Office Action Summary**	**Application No.** 10/052,712	**Applicant(s)** SHELL, JOHN W.
	Examiner Bennett Celsa	**Art Unit** 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-114* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction/Election

Status of the Claims

1. Claims 1-114 are currently pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 90, drawn to a "therapeutic agent comprising a selected candidate compound", classified in various classes or subclasses dependent upon the selected screened candidate compound (e.g. Proteins are in class 350 various subclasses).

II. Claims 1-89 and 99-114, drawn to a method of screening a combinatorial library, classified in class 435, subclass 6+.

III. Claims 91-92 (in part) and 93-98, drawn to treating (or preventing) "medical conditions associated with crystalline structure" (e.g. cataracts, cystic fibrosis, asthma etc.: see specification page 26) classified in class 514, subclass 912 as well as other classes and subclasses upon selection of biological agent and disease state.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the the process as claimed can be used to

make other and materially different product since the process is totally nondescript regarding the candidate compound structure and thus can make any prospective type of compound; and the product as claimed can be made by another and materially different process such as solid/liquid phase syntheses (e.g. of peptides/saccharide or nucleotides).

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product e.g. the use of allopurinol to treat gout .

Inventions II and III are drawn to methods which are independent and/or patentably distinct due to differences in method objective (assay vs. treatment) mileu (e.g. in vitro vs. in vivo) and reaction parameters (e.g. delivery; compositional components i.e. diluents vs. labels etc).

Because these inventions are distinct for the reasons given above:

a. have acquired a separate status in the art as shown by their different classification;

b. the manual/computer searches required for Groups I-III are different; and

c. because these inventions have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election/Restriction (For Groups I-III)

2. This application contains claims directed to the following patentably distinct species of the claimed invention: assays encompassing different patentably distinct species of:

A. "crystaline structure" (e.g. fibrils, ocular cataracts etc.);

B. "pathogenic mass" (e.g. atherosclerotic , cataract, neuritic, dendritic, kidney, gallstone etc.);

C. "endogenous human biomolecules" (e.g. peptides (i.e. amyloid, prion, CFTR, Charcot-Leyden, lenticular) , sterols (e.g. cholesterol) , uric acids or salts, calcium salts, cystalins, hemoglobins immunoglobulins etc.)

D. "detectable label" (e.g. fluorescent, UV, refractive index , colored etc.)

E. "candidate compound (e.g. peptide, or species of non-peptide etc.)

Which are patentably distinct compounds of diverse structure, physicochemical properties which are capable of separate manufacture and/or use and which are classifiable in different classes and subclasses and which require separately burdensome manual and/or computer classification, structure, name and/or bibliographic searches in their corresponding methods which are different and separately burdensome

Accordingly, applicant must elect BOTH:

A specific SINGLE species for EACH OF A-E recited above AND INDICATE CLAIMS READABLE THEREON.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Further Election/Restriction (For Group III)

Upon the selection of Group III applicant ***must further elect one disease species from among the "medical condition" species described in the specification table on page 26 including : cataracts, sickle cell anemia, Alzheimer's disease ... synovitis and indicate claims readable thereon..***

The individual method species are drawn to the treatment (or prevention) of patentably distinct disease states which differ in etiology, symptoms and/or treatment; and which further require different and separately burdensome manual/computer bibliographic searches in patent and literature databases.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
June 4, 2004